REMARKS

Status of the claims:

With the above amendments, claims 1, 8 and 13-14 have been amended and claims 1-20 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Support for the amendments to claims 1 and 13-14 can be found in the specification as filed at pages 11-12. Reconsideration is respectfully requested in light of the following remarks.

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of U.S. Patent No. 5,221,606 to Richardson (hereinafter Richardson) in view of U.S. Patent No. 5,464,755 to Bochner (hereinafter Bochner).

The Response is believed to overcome the existing rejections, and allowance of the pending claims is respectfully requested.

Abstract

In accordance with the Examiner's request to amend the abstract, Applicants herein amend the abstract as follows:

> The invention relates to devices and methods for detecting and identifying microorganisms comprising a porous body having regions of differing pore size, said regions being associated with different chromogens specific to enzymes produced by microorganisms. Devices and methods according to the present invention may be useful in the detection and identification of food and water borne microorganisms as well as in the detection of bacteria that may be associated with infection, such as urinary tract infection.

Applicants also attach the abstract to the back of this response.

Rejections under 35 U.S.C. § 103(a)

Claims 1-20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Richardson in view of Bochner. Applicants traverse.

The Examiner does not recite the teachings of Richardson in the present Office Action. The Examiner refers to the "teachings of Richardson above." Applicants have assumed that the Examiner wishes to incorporate the teachings of Richardson from the previous Office Action of August 20, 2008 and responds accordingly based upon the Examiner's characterization of Richardson set forth at that time. In the previously issued Office Action, the Examiner asserts that Richardson discloses chromogens adsorbed onto filter paper or a membrane to indicate the presence or absence of a particular enzyme for dipstick devices. *See* August 20, 2008 Office Action at 2. The Examiner also asserts that these enzyme substrates are selectively adsorbed onto cellulose and related polymers giving intense colors which are not leached from the polymer by water and that Richardson also teaches that the sample may be urine. *See* id. Further, the Examiner states that Richardson teaches that bacteria may be identified by the use of chromogenic substrates. *See* id. at 4. The Examiner states that Richardson does not teach the use of a number of chromogenic substrates, Mg^{2+}, buffers or layered filters. *See* id. at 2.

Further, the Examiner asserts that Bochner teaches a rapid test that includes enzymatic assays, stains, and filtration that is colorimetric. *See* March 9, 2009 Office Action at 3. In addition, the Examiner states that Bochner teaches multiple colorimetric substrates as well as a urinary tract pathogen test that uses multiple compartments. *See* id. Finally, the Examiner states that Bochner teaches the use of Mg^{2+} as a cofactor to enhance enzyme activity. *See* id.

The Examiner states that it would have been obvious to one of ordinary skill in the art to employ the device of Richardson and include any desired known selective substrates for their known function to identify bacteria, as taught by Bochner. Further, the Examiner asserts that "the filters of Richardson reads on the layers as claimed." *See* id.

Applicants traverse.

To establish a proper case of obviousness, one must apply the *Graham v. John Deere* factors. These factors include:

> *(A) Determining the scope and contents of the prior art;*
> *(B) Ascertaining the differences between the prior art and the claims in issue;*
> *(C) Resolving the level of ordinary skill in the pertinent art; and*
> *(D) Evaluating evidence of secondary considerations.*

See *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).

Moreover, recently in the *KSR* case, regarding obviousness, the Court held

> *Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See In re Kahn, 441 F. 3d 977, 988 (CA Fed. 2006) ([R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness).*

See *KSR International Co. V. Teleflex Inc. et al.* 127 S. Ct. 1727 (2007).

When the *John Deere* factors and the holding in *KSR* are considered in light of the rejection presented, one can only conclude the instantly claimed invention is non-obvious for the following reasons.

The Examiner has failed to present a *prima facie* case of obviousness. The prior art references (or references when combined) do not teach or suggest all of the claim

limitations. For example, and as detailed below, Richardson teaches the use of a filter paper to draw an insoluble chromogenic substrate out of an aqueous solution to identify the presence or absence of an enzyme. Richardson, therefore, does not teach or disclose a method for detecting and identifying microorganisms as claimed in claim 14 and claims dependent therefrom. Bochner fails to make up for the deficiencies of Richardson. Bochner also does not teach a device or method for detecting and identifying microorganisms as claimed in claims 1 and 14, respectively.

The Examiner asserts that Richardson teaches that bacteria may be identified by the use of chromogenic substrates on filters. However, the filter paper employed by Richardson is not used to identify bacteria, but rather simply to draw insoluble chromogens, which have been used to identify the presence of enzymatic activity *in an aqueous solution*, out of the solution for confirmation purposes only. In other words, the use of filter paper by Richardson is simply to confirm the end point of a completed reaction that occurred in solution, rather than as one of a plurality of layers in a solid state detection device. *See* Richardson at col. 1, line 57 to col. 2, line 6.

Further, claims 1 and 14 recite a porous body having *a plurality of regions of differing pore size* with said regions *being associated with a plurality of different chromogens* specific to enzymes produced by microorganisms (emphasis added). Richardson does not teach a porous body with a plurality of regions having differing pore sizes and said regions being associated with different chromogens for the purpose of filtering and identifying a plurality of microorganisms present in a single sample. Rather, Richardson discloses a filter paper that can be used to draw an insoluble chromogen from an aqueous solution. *See* Richardson at col.1, line 57 to col. 2, line 6.

Finally, the Examiner asserts that "the filters of Richardson read on the layers as claimed." Applicants respectfully disagree. The filters of Richardson are employed simply to adsorb chromogen which is present in an aqueous solution. In contrast, the plurality of regions of differing pore size according to the present invention are coupled to chromogens specific to enzymes produced by microorganisms. The arrangement of the regions of differing pore sizes that are coupled to chromogens specific to enzymes produced by microorganisms is such that smaller microorganisms may wick through the porous body and be trapped upon reaching a region with a particular pore size too small for the microorganism to pass through, which has been coupled to a chromogen specific to that type of microorganism. This step by step filtration system, which employs a plurality of regions with differing pore sizes to concentrate microorganisms onto the region containing the appropriate chromogen is not taught by Richardson.

Bochner does not make up for the deficiencies of Richardson. The Examiner asserts that Bochner teaches in column 7, lines 21-27 rapid tests including enzymatic assays, stains, and filtration that is colorimetric. However, Bochner acknowledges that these methods were deficient in that they did not allow for identification of the particular organisms that were present in the sample. *See* col. 7, lines 33-36. Therefore, Bochner employs an alternative method which includes the use of nutrition-supplemented media to provide a colorimetric indication of the type of bacteria present. In contrast, Applicants' claimed invention provides a device and method for detecting and identifying microorganisms using enzymatic assays that employs a porous body having a plurality of regions of differing pore size which are associated with a plurality of different chromogens which are specific to enzymes produced by microorganisms. Further, the

present invention is designed to be a rapid detection method and does not require the addition of any media supplemented with nutrients as innoculation of the bacteria is not required to identify the types of bacteria present in the sample. In contrast, Bochner requires an alternative method which includes using nutrition-supplemented media to provide a colorimetric indication of the type of bacteria present.

Additionally, the Examiner states that Bochner teaches in column 13 the use of multiple compartments to detect and distinguish between different pathogens. However, the multiple compartments taught in column 13, line 55 through column 14, line 15 are fundamentally different from the porous body having a plurality of regions of differing size which are associated with a plurality of different chromogens specific to enzymes produced by microorganisms. For example, each of the separate compartments taught in column 13 of Bochner are required as each compartment utilizes a different media for the specific growth requirements of the bacteria. Further, the different bacteria to be detected by the method disclosed in column 13, line 55 through column 14, line 15 of Bochner must remain separate and be pure cultures. In contrast, in a claimed embodiment of the present invention, a series of regions of differing pore sizes are used to identify multiple microorganisms present in a single sample. See claims 1 and 14. Furthermore, Bochner states at column 14, lines 5-7 that the disclosed multi-compartment tests "must be inoculated with pure cultures and therefore the medium is therefore *not useful for primary isolation from urine specimens*." (emphasis added). Accordingly, one can conclude that the multi-compartment tests are also not useful for any other non-sterile samples. Therefore, the multi-compartment test taught in Bochner would be wholly unsuitable for the detection of a plurality of microorganisms present in a single sample.

Because neither Bochner nor Richardson allow for the detection of a plurality of microorganisms present in a single sample, Bochner combined with Richardson cannot render *prima facie* obvious the presently claimed invention.

Moreover, one of ordinary skill in the art would have no reason to combine the references as Richardson does not teach a device or method for detecting and identifying microorganisms. Bochner does not cure that deficiency but rather teaches away from using enzymatic tests with multiple compartments to identify and differentiate between microorganisms present in a sample. Further, based upon the teaching of Bochner, one of ordinary skill in the art would have no expectation of success in developing a rapid testing device using enzymatic activity with stains, filtration that is colorimetric, and multiple layers or compartments. For at least these reasons, claims 1-20 are not obvious in view of the cited references. Applicants respectfully request reconsideration and withdrawal of these rejections.

As to the Examiner's statement that identifying bacteria with known chromogens is old and that filtering bacteria with buffers is old, Applicants point Examiner to the passage of *In re Kahn* cited by the Supreme Court in *KSR* which states:

> *[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*

In re Kahn, 441 F. 3d 977, 988 (Fed. Cir. 2006).

Applicants assert that Examiner's statements regarding the identification of bacteria with known chromogens and the filtration of bacteria with buffers are mere conclusory statements not supported by the cited references. Therefore, the Examiner has

failed to establish a *prima facie* case of obviousness for claims 1-20 and withdrawal of the rejection is warranted and respectfully requested.

With respect to the two additional references cited by the Examiner, U.S. Patent No. 5,714,343 to Tuompo et al. ("Tuompo") and U.S. Patent No. 6,846,648 to Maes, Applicants submit the following remarks.

Tuompo differs from embodiments of the present invention in that it is concerned with the detection of microorganisms containing dehydrogenase activity in a sample. *See* Tuompo col. 2, lines 56-59. The method of Tuompo cannot differentiate between multiple microorganisms present in a single sample, it may only detect the presence or absence of a microorganism with dehydrogenase activity. *See* id.

Maes describes a procedure that utilizes a chaotropic agent to disrupt the stabilizing hydrogen bonds of a sample to yield better detection with a labeled reagent, such as an antibody specific for a microorganism. *See* Maes col. 4, lines 30-35. Further, the method according to Maes is not capable of detecting and differentiating a plurality of microorganisms present in a single sample. *See* id.

As demonstrated by the foregoing remarks, neither Tuompo nor Maes describe a device for detecting and identifying a plurality of different microorganisms present in a single sample comprising a porous body having a plurality of regions of differing pore sizes, each of the said plurality of regions being associated with a plurality of different chromogens specific to enzymes produced by microorganisms.

CONCLUSION

With the above amendments and remarks, Applicants believe that all objections and/or rejections have been obviated. Thus, each of the claims remaining in the application is in condition for immediate allowance. A passage of the instant invention to allowance is earnestly solicited.

Applicants respectfully request a two month extension of time and enclose the required fee herewith. Applicants believe that no additional fee is necessary, however, should a fee be deemed to be necessary, the Commissioner is hereby authorized to charge any fees required by this action or any future action to Deposit Account No. 16-1435.

Should the Examiner have any questions relating to the instant application, the Examiner is invited to telephone the undersigned at (336) 607-7442 to discuss any issues.

Respectfully submitted,

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